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December 17, 2018

VIA ECF

Honorable Judge Claire C. Cecchi
United States District Court
District of New Jersey
Martin Luther King Building & U.S. Courthouse
50 Walnut Street
Newark, NJ 07101

In Re: Proton-Pump Inhibitor Products Liability Litigation
2:17-md-2789 (CCC)(MF) (MDL 2789)

Dear Judge Cecchi,

Consistent with Case Management Order No. 29, Plaintiffs respectfully submit this letter to update the Court on the status of various discovery issues in advance of the upcoming December 19, 2018 status conference. While the parties have conferred on the issues below, the PSC believes we have reached an impasse on several discovery requests that require the Court's intervention and, which if left unresolved, threaten our ability to prepare for trial. Thus, we respectfully ask the Court to order the implicated Defendants to promptly produce the requested documents and provide dates for the requested depositions in February and March of 2019.

Deposition Scheduling

The PSC continues to serve deposition notices for defense witnesses pursuant to CMO Nos. 17-20. Most Defendants have responded promptly, providing dates within a week or two of our requests. Unfortunately, AstraZeneca appears unable to do so. Indeed, from October 18 through November 15, 2018, AstraZeneca was served with 17 deposition notices. While we later learned that one of the witnesses was deceased and another could not be found, the excuses and hurdles for the 15 depositions we initially noticed between 30-60 days ago, are as follows:

- AstraZeneca has provided dates for only 5 of the 15 remaining witnesses.[1]
- For 5 of these 15 witnesses, AstraZeneca is still "waiting to hear back" from the witness.

[1] Notably, 2 of these deposition dates were not offered until the close-of-business on December 14, 2018—after the Joint Report and Agenda were filed and on the original due date for this letter brief concerning open discovery issues.

- For 4 of these 15 witnesses, we have been told these overseas former witnesses refuse to appear voluntarily.
- Of these former employees who are overseas, AstraZeneca has compounded the problems by refusing to provide us with last known contact information for the witnesses.[2] Thus, the PSC has been forced to hire private investigators to locate these witnesses and will be going through effect Hague Service on those witnesses.
- There is 1 witness, Charlotta Klockare, who is a current employee, however, AstraZeneca will only agree to produce her in India.

These are simply the first 17 deposition notices that were served between 30-60 days ago. AstraZeneca's responses and its failure to secure dates in a timely manner can only be viewed as obstructionist, and should not be permitted. Curiously, while AstraZeneca fought vigorously for deposition "soft caps," its persistent stonewalling and interjection of obstacles has all but ensured the PSC will never be able to conduct the number of depositions they bargained for if AstraZeneca is permitted to continue with this behavior.[3]

While we appreciate that many of the witnesses are former employees located outside the United States, given the extended delay, we do not believe AstraZeneca is making a good faith effort to secure these depositions or get cooperation from these former employees. Notably, AstraZeneca has known that many of these individuals were potential deposition witnesses for several months. All of the witnesses are individuals for which we requested custodial file productions long ago and many of them are witnesses previously identified by AstraZeneca as individuals with substantial knowledge about the products at issue. There is simply no reason why it should take 2 months to secure deposition dates. As noted above, at the rate at which AstraZeneca is providing deposition dates, we will never be able to complete discovery by the deadlines set forth in CMO No. 21. Therefore, we ask the Court to order the following:

- For all witnesses that are current employees, AstraZeneca shall produce the witness within 30 days of being noticed by the PSC and on one of two dates offered by the PSC;

- For all witnesses that are former employees, AstraZeneca shall: (a) produce the witness for deposition within 30 days of being noticed by the PSC, or (b) within 5 days of being noticed, AstraZeneca will provide last known address or show cause under the law why doing so is impermissible. If the PSC is required to subpoena the witness domestically or overseas, the witness will be produced and the Court will enforce any subpoena on the date noticed by the PSC. To the extent

[2] AstraZeneca contends that Sweden's privacy laws prevent them from disclosing this information, however, to date they have provided no authority for this position nor have they identified which law they seek to hide behind. Moreover, it is not apparent that all of the witnesses reside in Sweden. Indeed, 1 of the 4 witnesses who will not voluntarily appear resides in the United Kingdom.

[3] By contrast, the Takeda Defendants have provided deposition dates within 1-2 weeks of receiving our deposition notices. Additionally, they have agreed to produce foreign witnesses in the United States.

> AstraZeneca represents any witnesses who are former employees and for whom subpoenas have needed to be issued to compel the witness's production the Court will take under advisement relief the PSC may seek, including to extend the discovery deadline or other relief the PSC may seek under the circumstances as they develop.

The PSC respectfully submits that anything short of setting deadlines will result in AstraZeneca continuing to manipulate the system to prevent depositions from going forward as needed to meet the deadlines of CMO No. 21.

Production of Clinical Documents and Data

This issue relates to the document production from the AstraZeneca Defendants. As the Court may recall, the PSC served their first Request for the Production of Documents in September 26, 2017. Included in this request was a demand for the production of clinical trial documents and data relating to Prilosec and Nexium. Such documents are critical, as they contain significant information relating to the safety and efficacy of the PPIs at issue. In connection with the parties' discovery negotiations and initial 30(b)(6) depositions, AstraZeneca supplied a list of more than 1,500 clinical trials involving Prilosec and/or Nexium. Over the last year, AstraZeneca has made several productions of clinical documents and the PSC's understanding was that the clinical data production was to be completed in October 2018.

Unfortunately, after completing a rigorous review of this production and comparing it to the list of clinical trials provided by AstraZeneca, we have found this production to be woefully deficient. Indeed, we are missing information on hundreds of clinical trials that should have been produced—particularly because clinical trial information is usually subject to long-term retention policies and is kept in centralized databases and locations. Nevertheless, cognizant of AstraZeneca's production burdens, we have narrowed the list of 1,568 studies to only 181, for which we are requesting additional information. On October 24, 2018, we provided AstraZeneca with a list of 83 Prilosec studies for which were missing critical information. Notably, the total list of Prilosec studies identified by Defendant included approximately 930 studies. An additional 638 Nexium studies were also identified by AstraZeneca, of which we narrowed our request to 98.[4]

Specifically, the additional information sought by Plaintiffs includes clinical study reports for certain trials, as well as case report forms and SAS[5] datasets for select studies. Case Report Forms ("CRFs") are critical in that they are the means by which investigators report and describe adverse events that occur during the course of a clinical trial. It is important for Plaintiffs to review such forms to ensure that adverse events relating to kidney injury were not missed and were properly characterized when reported to the FDA and in medical literature. SAS datasets are also very important because analysis of this data is done for safety signal detection, as well as statistical

[4] The PSC provided this list of Nexium studies to Defendant on November 1, 2018.

[5] "SAS" stands for Statistical Analysis System, which is the primary means by which Defendants' statisticians analyze clinical trial data and other reported adverse events to determine if there are safety signals. The datasets requested are the compilations of data that are analyzed by SAS.

analysis provided to the FDA in support of applications to the Agency for approval to market a prescription drug. SAS data is routinely produced in discovery, pursuant to applicable protective orders, and is needed by Plaintiffs' experts to analyze adverse events across multiple studies or groupings of studies, where appropriate.

As Your Honor may recall, this issue was initially on the Agenda for the last status conference, however, based on representations made by AstraZeneca's counsel prior to the conference that it would produce the material at issue, Plaintiffs agreed not to raise the issue at the hearing. Specifically, AstraZeneca's counsel stated that to the extent those documents existed, AstraZeneca had no objection to producing them. However, during a recent meet and confer, it became clear that Defendant's position has changed and it is now only willing to produce Case Report Forms for those studies where AstraZeneca is unable to locate SAS datasets. This change in position is unacceptable and seems designed to prevent the PSC from obtaining relevant information. The documents and information sought are not equivalent nor interchangeable. As noted above, the Case Report Form is a documentation of an adverse event made by the scientific investigator during the course of a clinical trial. By contrast, SAS data is simply how AstraZeneca sought to record, and ultimately report, the event. Indeed, data reported in a Case Report Form is frequently evaluated, adjudicated, and changed by the manufacturer or its representatives, before it is memorialized in a SAS dataset. Plaintiffs need both categories of information to evaluate whether adverse events in clinical trials were properly reported. Additionally, we have yet to receive the missing clinical study reports we first began reporting to AstraZeneca in October.

The documents and information described above is important for expert analysis and depositions of AstraZeneca's clinical and research personnel. Plaintiffs respectfully request that the Court order these productions be completed within 30 days.

The Timing and Methodology of the Production of AstraZeneca's Adverse Event Database

At issue is the timing and methodology used to produce an extract of AstraZeneca's adverse events database. If a physician suspects a drug may have caused an adverse event in one of her patients, she may elect to report it directly to the manufacturer or to the FDA. The manufacturer, in turn, is required by federal regulations, to report any adverse events associated with its drugs to the FDA. Manufacturers traditionally keep all the data surrounding these reports and events in an adverse event database. These databases are typically very large and complex, and when produced in litigation, are generally provided as Excel spreadsheets containing select information that has been extracted from the database. It is important to note that the PSC and AstraZeneca have already agreed on the search terms to be run against the database, as well as the fields of information that will be produced. The present dispute is over the fields that will be searched to find relevant adverse event reports and the timing of the production.

By way of background, AstraZeneca has already made a production from this database. However, it did so without consulting the PSC, utilizing self-selected search terms. After review of adverse event reports obtained from the FDA and consultation with its own experts, Plaintiffs proposed an expanded list of search terms, which after some negotiation, AstraZeneca has agreed to utilize. However, the parties have been unable to agree on which fields within AstraZeneca's database will be searched.

Plaintiffs have requested that 3 fields be searched. The first field is what is referred to as the "Case Narrative" field. This field contains the description of the adverse event *as reported by the physician*. The second field is called "Event As Reported," and contains one or more adverse events *selected by the manufacturer* from the Case Narrative Field. The third field is called "Preferred Term," and contains an official medical term derived from a medical dictionary for the event being reported by the manufacturer. Again, this term is *selected by the manufacturer*. Plaintiffs have requested that all 3 fields be searched—this way we are assured of capturing events that may have been reported by the physician that were not captured by the company in its evaluation of the event. By contrast, AstraZeneca insists that it should only search the Event As Reported and the Preferred Term fields, which contain events selected by the manufacturer, rather than the description of the reporting physician.

AstraZeneca has represented to the PSC that AstraZeneca's methodology will result in 21,065 adverse event case reports. By contrast, the PSC's proposed methodology will result in 34,442 adverse event case reports—a difference of 13,377 reports. AstraZeneca has objected to using Plaintiffs' proposed methodology on the basis that it is too burdensome, claiming that it will result in it having to review and redact "thousands" of irrelevant reports. However, when pressed, defense counsel admitted that AstraZeneca has not actually analyzed any of these reports—thus, its claim is purely speculative. Moreover, the vast majority of redactions do not occur within a case narrative, rather the redactions can be done globally within other fields that are not even produced to Plaintiffs (e.g., doctor identifying information and telephone number).

The PSC is suspect of AstraZeneca's claims because it has been evasive about this production from the start. For example, and as described above, AstraZeneca initially made a production from its adverse events database based on its self-selected search terms, which were only run against the Preferred Terms field. This search yielded only 3,269 cases. After, the PSC expanded the search terms and AstraZeneca included the Event as Reported field, the number of cases has increased to 21,065.[6] Notably, when Plaintiffs first requested that AstraZeneca search the Case Narrative field so that we could capture events as reported by the physician, defense counsel represented that the field *was not searchable at all*. After we conducted our own investigation and learned that the filed is indeed searchable, AstraZeneca revised its position to say that while the field is searchable, it is more difficult to search and will result in too many irrelevant reports. As noted above, AstraZeneca has provided no support for its position that the additional 13,377 reports generated by using the PSC's methodology will be mostly irrelevant.

Additionally, AstraZeneca has intimated that it will take months to produce an extract from the adverse event database. This is largely due to the fact that certain fields will need to be redacted. However, the large majority of redactions are of entire fields (e.g., Reporter's Name and Address) which can be withheld or redacted globally. While, Plaintiffs acknowledge that there are instances when a doctor's name may need to be redacted from a narrative field of a report, we believe this is for the minority of reports. Indeed, in its prior production, AstraZeneca only had to

[6] The PSC appreciates that the parties disagree about whether all search results are relevant. While AstraZeneca's initial search term list was limited to specific injuries exactly as described in the MedDRA dictionary, the PSC's search term list included a broader range of kidney injuries and conditions symptomatic of kidney injury.

perform redactions in approximately 2,990 of the 17,315 narrative fields it provided. Thus, AstraZeneca exaggerates its burden of redaction.

Adverse event data will be analyzed by experts and will be the subject of depositions and AstraZeneca should not be allowed to manipulate the methodology so as to exclude potentially relevant adverse events. Furthermore, adverse event data is a corner stone of the PSC's case alleging that there were signals of injuries (i.e. adverse events) known to AstraZeneca, for which the company failed to warn the public or the medical community.

Notably, the Takeda Defendants offered to produce their entire adverse event database. While Plaintiffs are not asking this of AstraZeneca, we are requesting that the Court order AstraZeneca to utilize the PSC's proposed methodology and to produce the its highly relevant adverse database production within 14 days.

PSC Request for Leave to File a Motion to Compel Discovery Responses

On December 7, 2018, the PSC sent a letter to Defendants (annexed hereto as Exh. A) in follow-up to their responses to Plaintiffs discovery requests regarding affirmative defenses they have raised and about which they made explicit representations in a submission to the Court dated April 27, 2018 [Doc. No. 199]. To date, only the GSK Defendants have requested to confer on this request. The remaining Defendants have not responded. For the reasons set forth in Exhibit A, we respectfully request leave to file a motion to compel a complete response from Defendants.

Supplementation of Custodial and Non-Custodial Files

As the Court is aware, it previously instructed Defendants to supplement its initial Regulatory productions through December 31, 2017, in light of the fact that the products at issue are still on the market. With another year passing, we recently requested that Defendants supplement their document productions through December 2018 for the following limited categories:

1. Regulatory file;
2. Pharmacovigilance/Safety Signal Detection meeting minutes as well as any reporting to regulatory authorities; and
3. Any custodian previously requested who is still a current employee or who left the company between the time of last collection and December 2018.

This supplementation is critical for two reasons. First, the PPI products at issue are still on the market and have been subject to heightened scrutiny by the medical community over the last year. Thus, the likelihood of additional analysis and discussion of the products among Defendants' employees and with regulatory agencies is greatly increased. Second, there are numerous depositions being scheduled over the next several months and many of the witnesses at issue had their documents collected in the Summer and Fall of 2017—more than one year ago. Their files should be supplemented to avoid having to take second depositions of witnesses.

The AstraZeneca and Takeda Defendants have agreed to supplement these non-custodial and custodial sources. We are still in discussions with other Defendants regarding this request.

We thank the Court for its time and courtesy, and look forward to discussing these issues with Your Honor at the Court's convenience.

Respectfully submitted,

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cc: All Counsel of Record (via ECF)